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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|--|-----------------------------|
| 10/566,100 | 10/26/2006 | Antoni Torrens Jover | 283628US0PCT | 9565 |
| 22850 | 7590 | 01/07/2010 | | |
| OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | EXAMINER RAMACHANDRAN, UMAMAHESWARI | |
| | | | ART UNIT 1627 | PAPER NUMBER |
| | | | NOTIFICATION DATE 01/07/2010 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

| | | | |
|------------------------------|---|---|--|
| Office Action Summary | Application No. 10/566,100 | Applicant(s) TORRENS JOVER ET AL. | |
| | Examiner UMAMAHESWARI RAMACHANDRAN | Art Unit 1627 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- (1) compounds with neuropeptide Y (NPY) receptor affinity
- (2) compounds with 5-HT6 receptor affinity
- (3) use of a medicament in combination of compounds with neuropeptide Y (NPY) receptor affinity and compounds with 5-HT6 receptor affinity for regulation of appetite, for maintenance, increase or reduction of body weight, for prophylaxis and/or treatment of disorders related to food ingestion, preferably for prophylaxis and/or treatment of obesity, anorexia, cachexia, bulimia, diabetes, preferably type 11 diabetes (non-insulin-dependent diabetes mellitus), for prophylaxis and/or treatment of gastrointestinal tract disorders, preferably of the irritable bowel syndrome, for prophylaxis and/or treatment of Peripheral Nervous System Disorders, for prophylaxis and/or treatment arthritis, for prophylaxis and/or treatment of epilepsy, for prophylaxis and/or treatment of anxiety, for prophylaxis and/or treatment of panic, for prophylaxis and/or treatment of depression, for prophylaxis and/or treatment of bipolar disorders, for prophylaxis and/or treatment of cognitive disorders, for prophylaxis and/or treatment of memory disorders, for prophylaxis and/or treatment of cardiovascular diseases,

for prophylaxis and/or treatment of senile dementia processes, for prophylaxis and/or treatment of neurodegenerative disorders, preferably Alzheimer's disease, Parkinson's disease, Huntington's disease and/or multiple sclerosis, for prophylaxis and/or treatment of schizophrenia, for prophylaxis and/or treatment of psychosis, for prophylaxis and/or treatment of infantile hyperkinesia (ADHD, attention deficit/ hyperactivity disorder), for prophylaxis and/or treatment of pain, for prophylaxis and/or treatment of hypertensive syndrome, for prophylaxis and/or treatment of inflammatory diseases, for prophylaxis and/or treatment of immunologic diseases, for improvement of cognition.

The species are independent or distinct because the species of the compounds listed in the claims are structurally different and the search for each species of the compounds listed would represent undue burden on the Office. For example, as cited in the Specification in para 007, there are at least six different receptor subtypes named Y1-Y6 in NPY binding receptor family, each NPY receptor subtype is generally associated to a different biological activity. There are a large number of agonists, antagonist compounds that fall under the category of 5-HT6 receptor affinity compounds. Also, applicants' claim the use of combination of compounds with neuropeptide Y (NPY) receptor affinity and compounds with 5-HT6 receptor affinity for treating a variety of diseases as listed above. Each disease has a different and distinct etiology and pathophysiological manifestations, and that each is differently treated. Such is sufficient to indicate that each of the methods of treating the presently claimed disease states is differently searched in the patent and non-patent literature and that a

search for one disease will not necessarily result in a comprehensive search of any one or more of the diseases listed. As a result, an undue burden would be placed on the Examiner to search each of Applicant's presently claimed species. Claims 1-5 are towards an active substance combination of NPY and 5-HT6 receptor affinity compounds. Claims 6-7 are towards a medicament comprising the active substance combination claimed in claims 1-5, claims 8-33 are towards the use of such active substance combination claimed in claims 1-5 and claims 34-45 are towards the pharmaceutical formulation of active substance combination claimed in claims 1-5. Claims 1-45 are generic with respect to the medicament comprising the compounds.

Applicant is required to elect a single species for compounds with neuropeptide Y (NPY) receptor affinity (e. g. 2-[4-(2-Hydroxymethyl-phenylamino)-piperidin-1-yl]-N-quinolin-8-yl-acetamide), a single species for compounds with 5-HT6 receptor affinity (e.g. EMD-386,088), a single species for the disease (e. g. for regulation of appetite). Please note that there are improper multiple dependent claims and use claims (8-33) (see MPEP 2173.05 use claims) in the claim set.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Because the restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See MPEP § 812.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to UMAMAHESWARI RAMACHANDRAN whose telephone number is (571)272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1627

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627